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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,227	08/27/2001	Sei-Yu Chen	DEX-0230	4313
26259	7590	03/02/2004	EXAMINER	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			BLANCHARD, DAVID J	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/940,227	CHEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David J Blanchard	1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 9, 10 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 10 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-8 and 11-16 have been cancelled in the Paper filed 12/22/2003.
2. Claim 17 has been added in the Paper filed 12/22/2003.
3. Claims 9, 10 and 17 are pending and under examination.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. This office action sets forth New Grounds of Rejection.

### **Information Disclosure Statement**

6. Applicant is thanked for providing the dates for references AB (9/1/1999) and AC (8/4/1999).

### ***Rejections Withdrawn***

7 The rejections (a-d) of claims 9 and 10, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn in view of the amendments to the claim.

8. The rejection of claims 9 and 10 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the

Art Unit: 1642

application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims.

### ***Response to Arguments***

9. The rejection of claims 9 and 10 and new claim 17 under 35 U.S.C. 112, first paragraph, lack of enablement is maintained.

The response filed 12/22/2003 has been carefully considered, but is deemed not to be persuasive. Applicants argue that claims 9 and 10 have now been amended to recite that SEQ ID NO:15 is differentially expressed in cancer cells, however, the arguments do not address the enablement issue as to whether or not the polypeptide encoded by SEQ ID NO:15 or the polypeptide of SEQ ID NO:83 are either over expressed or under expressed in a specific disease state. Further, the arguments in the response do not address whether or not the mRNA encoding SEQ ID NO:83 is expressed or even differentially expressed in cancer cells. Applicant has provided no evidence of record (i.e., ELISA or western data), which to show that a polypeptide encoded by SEQ ID NO:15 or the polypeptide set forth as SEQ ID NO:83 are either over expressed or under expressed in a specific, diseased tissue compared to a healthy tissue control, for example, and there is no evidence of record demonstrating that the mRNA encoding SEQ ID NO:83 is expressed or differentially expressed in cancer cells. In fact, the teachings of Fu et al, Powell et al, Vallejo et al and Jang et al cited in the office action mailed 9/23/2003 clearly demonstrates that the predictability of protein

Art Unit: 1642

translation and its possible utility as a diagnostic are not necessarily contingent on the levels of mRNA expression. Therefore, in the absence of a direct correlation between the up-regulation of transcription and translation of the polypeptide encoded by SEQ ID NO:15 or the polypeptide set forth as SEQ ID NO:83 associated with a specific disease state, one of ordinary skill in the art would be unable to use an antibody that binds the polypeptide encoded by SEQ ID NO:15 or the polypeptide set forth as SEQ ID NO:83 in a diagnostic or therapeutic setting. Applicant's statement on page 6 of the response "a polypeptide encoded by SEQ ID NO:15, which is differentially expressed in cancer cells" is insufficient to overcome this rejection in the absence of supporting evidence. For these reasons, the rejection of claims 9 and 10 is maintained and new claim 17 is rejected.

***New Grounds of Rejection***

10. Claims 9, 10 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

a. Claims 9, 10 and 17 are indefinite for reciting "which is differentially expressed in cancer cells" in claim 9. It is unclear if the polypeptide encoded by SEQ ID NO:15 (i.e., SEQ ID NO:83) is differentially expressed in cancer cells or if SEQ ID NO:15 is differentially expressed is differentially expressed in cancer cells. Does the phrase "which is differentially expressed in cancer cells" mean that SEQ ID NO:15 is

Art Unit: 1642

differentially expressed in cancer cells or does the phrase mean that the polypeptide encoded by SEQ ID NO:15 is differentially expressed in cancer cells?

11. Claims 9, 10 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The amendment filed 12/22/2003 introduces NEW MATTER into the claims. The specification does not support the broad recitation that SEQ ID NO:15 is differentially expressed in just any cancer cells. It is noted on page 144, lines 15-17 that over expression of SEQ ID NO:15 (Lng140) mRNA was only found in 53% of lung cancer tissue as compared to normal or healthy lung tissue (see also Table 2). Additionally, Table 2 shows that Lng140 is not differentially expressed or even expressed in several cancerous tissues including bladder, kidney, liver, mammary, prostate, skin, testis, and thyroid. Therefore, the full scope of the recitation that SEQ ID NO:15 (Lng140) is differentially expressed in cancer cells is not supported by the disclosure. Applicants are requested to specifically point out where support for this limitation can be found or remove this limitation from the claims.

### ***Conclusions***

12. No claim is allowable.

13. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at (571) 272-0827 from 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871.

Official papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published


Application/Control Number: 09/940,227

Page 7

Art Unit: 1642

in the Official Gazette, 1096 OG 30 (November 15, 1989). The official fax number for Group 1600 where this application or proceeding is assigned is (703) 872-9306.

Respectfully,  
David J. Blanchard  
(571) 272-0827



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER